

Application No. 10/098,683  
Amendment dated April 16, 2004  
Reply to the Office Action of October 20, 2003

### REMARKS

Applicant cancelled claims 66 and 91, and amended claims 58, 67, 83, and 92 to further define Applicant's claimed invention.

In the Office Action, the Examiner objected to the Amendment dated August 5, 2003 under 35 U.S.C. § 132 as introducing new matter into the disclosure. The Examiner rejected claims 54-103 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement for a bone fusion implant containing a combination of bone morphogenetic protein and a fusion promoting material other than bone and other than bone morphogenetic protein in a hollow interior of the bone fusion implant. Applicant respectfully traverses the Examiner's objection to the August 5, 2003 amendment and written description requirement rejection under 35 U.S.C. § 112, first paragraph.

According to the MPEP, "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." (MPEP § 2163(I), page 2100-159, col. 1 (February 2003)). In the specification, Applicant discloses that the device may be "coated with *materials* to promote bone fusion." (Specification, page 5, lines 5-9, and page 13, line 35 to page 14, line 3 (emphasis added)). Accordingly, Applicant submits that there is adequate support for the device being coated with more than one fusion promoting material.

Applicant further discloses examples of fusion promoting materials, including "hydroxyapatite, hydroxyapatite tricalcium phosphate, or bone morphogenic protein." (Specification, page 14, lines 3-6). Hydroxyapatite and hydroxyapatite tricalcium phosphate are two examples of fusion promoting materials "other than bone" and "other than bone morphogenetic protein." Accordingly, Applicant submits that there is adequate support for a combination of bone morphogenetic protein and a fusion promoting material other than bone and other than bone morphogenetic protein being in at least a portion of the hollow interior.

Applicant submits that one skilled in the art would reasonably conclude that Applicant had possession of the claimed invention at the time the present application

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was filed. Accordingly, Applicant submits that the objection to the amendment of August 5, 2003 as introducing new matter, and the rejection of claims 54-103 for lack of written description have been overcome.

The Examiner rejected claims 54-103 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicant respectfully traverses the rejection and submits that the rejection was improperly made. The MPEP directs that the language of any enablement rejection "should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact." (MPEP § 2164.04, page 2100-183, col. 2 (February 2003)). Applicant respectfully submits that the Examiner's rejection does not conform to the MPEP guidelines quoted above.

Even if the rejection did conform to MPEP guidelines, Applicant submits that the limitation objected to by the Examiner in claims 54 and 79 is enabled. Applicant teaches in the specification that hydroxyapatite and hydroxyapatite tricalcium phosphate are two examples of fusion promoting materials. Hydroxyapatite and hydroxyapatite tricalcium phosphate are materials "other than bone" and "other than bone morphogenetic protein." According to the MPEP, "[a] patent need not teach, and preferably omits, what is well known in the art." (MPEP § 2164.01 "Test of Enablement," page 2100-179, col. 1 (February 2003)(citing *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991))). Applicant further submits that one skilled in the art would understand that coating a device with "materials" can include coating the device with more than one fusion promoting material. Accordingly, Applicant submits that there is adequate support and enablement for a combination of bone morphogenetic protein and a fusion promoting material other than bone and other than bone morphogenetic protein being in at least a portion of the hollow interior as would be recognized by one skilled in the pertinent art.

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Applicant submits that independent claims 54 and 79 are patentable and that dependent claims 55-78 and 80-103 dependent from one of independent claims 54 and 79, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the amendments to the claims and preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

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Dated: 4/16/04

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